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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,234	09/19/2003	Alberto Garavani	206,272	8486

7590 12/29/2006

JAY S. CINAMON
ABELMAN, FRAYNE & SCHWAB
150 East 42nd Street
New York, NY 10017

EXAMINER	
GHALI, ISIS A D	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/29/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/666,234	GARAVANI ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-25 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/16/2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' IDS filed 06/16/2004.

Claims 1-25 are pending and included in the prosecution.

Priority

1. If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage

commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference

in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-5, 7-23 of copending Application No. 10/104,410. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the referenced copending applications and would be covered by any patent granted on the copending applications since the referenced copending applications and the instant application are claiming common

subject matter as follows: the present claims and the conflicting claims in the copending application are directed to patch comprising support layer; an adhesive layer comprising adhesive polymer, hydrocolloid, hyaluronic acid and chondroitin sulphate; and removable protective layer, and method of its production.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-10, 16-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 302 536 ('536) in view of US 5,631,011 ('011) and the article by Fialkova et al.

The present claim 1 requires a patch comprising support layer, protective layer, and adhesive layer comprising adhesive polymer, hydrocolloid, hyaluronic acid or its salts, and chondroitin sulfate or its salts.

EP '536 teaches a wound dressing for treating wounds comprises polyurethane layer 11 that represents the support layer (page 5, lines 35-36); silicone coated release paper that represents the removable protective layer (page 3, lines 48-50; page 5, lines 33-35); and an adhesive layer comprising mixture of hydrocolloids represented by layer 14 (page 3, lines 10-11). The reference disclosed that the hydrocolloid mixture forms from about 10 to 65% by weight or more of the adhesive layer, and comprises mixture of sodium carboxymethyl cellulose and pectin, as claimed in claims 8 and 9, (page 3, lines 10-11, example 1; page 8, lines 46-49). The adhesive layer comprises pressure sensitive adhesive polymers including polyisobutylene and styrene isoprene copolymer, wherein the polyisobutylene has MW between 36,000 to 58,000, as claimed in claims 13-15 (page 2, lines 39-42). The total weight of the pressure sensitive adhesive polymer mixture forms between 34.5 to 40% by weight of the adhesive layer (examples 12 and 17). The adhesive layer contains small amounts of active agents (page 3, lines 37-42). The adhesive layer further comprising mineral oil in an amount ranges from 5 to 9.5% by weight, as claimed in claims 16-18 (examples 1, 16-23). The dressing is prepared by a process comprising the steps of mixing the powdered ingredients, extruding the resulting dough while it is hot on silicon coated release paper, and then

laminating the adhesive layer to impermeable polyurethane coating (page 4, lines 7-24; example 1; page 8, lines 50-58).

EP '536 does not teach the adhesive layer comprises hyaluronic acid or its salts and chondroitin sulfate or its salts

US '011 teaches tissue treatment composition that can be provided impregnated in a film or sheet or impregnated in cellulose flat matrix, the composition comprising polysaccharide/polyglycan (abstract; col.3, lines 50-57; col.5, lines 50-64; col.12, claim 6). The preferred polysaccharide/polyglycan is hyaluronic acid and its high molecular weight sodium hyaluronate salt because it exists in extracellular spaces of all tissues, hence its application results in temporary increase of the local concentration of endogenous materials without any physiological detrimental effects, and further it plays role in wound healing by influencing the migration of granulation tissue cells (col.3, lines 64-66; col.4, lines 3-6, 18-19; col.12, claims 1-3).

Fialkova et al. teach that the local administration of chondroitin sulfate to a cutaneous wound shows stimulation of regeneration of the damaged cutaneous tissues (abstract).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide the patch disclosed by EP '536 that comprises adhesive layer comprises adhesive polymer, hydrocolloid, and small amounts of therapeutic agents, and add the high molecular weight hyaluronic acid to the wound dressing as disclosed by US '011 motivated by the teaching of US '011 that the high molecular weight hyaluronic acid is preferred in wound healing compositions because it

exists in extracellular spaces of all tissues, hence its application results in temporary increase of the local concentration of endogenous materials without any physiological detrimental effects, and further it plays role in wound healing by influencing the migration of granulation tissue cells; and further one having ordinary skill in the art would add chondroitin sulfate to the wound dressing as taught by Fialkova motivated by the teaching of Fialkova that chondroitin sulfate shows stimulation of regeneration of the damaged cutaneous tissues, with reasonable expectation of having wound dressing comprising adhesive layer comprising hydrocolloid and adhesive polymer and further comprising hyaluronic acid and chondroitin sulfate wherein the dressing stimulates the healing and regeneration of the wound and promotes granulation tissue formation without any detrimental effects.

The combined teachings of the references do not teach the concentrations of hyaluronic acid and chondroitin sulfate in the adhesive layer, or sodium salt of chondroitin sulfate. However, the claimed concentrations of hyaluronic acid and chondroitin sulfate, as well as the specific sodium salts of chondroitin sulfate do not impart patentability to the claimed composition, absent evidence to the contrary.

The combined teachings of the references do not teach the exact molecular weight of hyaluronic acid. However, US '011 teaches that preferred hyaluronic acid is high molecular weight sodium hyaluronate.

The reference does not teach the temperature at which the extrusion is performed. The temperature of extrusion does not impart patentability to the claimed process. In any events, EP '536 disclosed the extrusion of the dough while hot (page 5,

line 27), and applicant shows no unexpected results obtained from the specific claimed temperature.

7. Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '536 in view of US '011 and Fialkova et al. as applied to claim1, 3-5, 7-9, and 13-23 above, and further in view of US 6,190,689 ('689).

The teachings of EP '536 combined with US '011 and Fialkova et al. are discussed above. The references in combination do not teach the inclusion of saccharose in the adhesive composition.

US '689 teaches a transdermal or topical device comprising pressure sensitive adhesive composition comprises a substances that are water soluble, meltable, adhesive at room temperature, and are known to cause no skin irritation or allergic reaction even with prolonged application on human skin (abstract; col.3, lines 18-24, 58-64). These substances include saccharose (col.3, lines 24-32).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a patch comprising adhesive layer comprising adhesive polymer, hydrocolloid, hyaluronic acid, and chondroitin sulfate, as taught by the combined teaching of EP '536 with US '011 and Fialkova et al., and add saccharose to the composition of the adhesive layer as disclosed by US '689, motivated by the teaching of US '689 that saccharose is water soluble, meltable, adhesive at room temperature and known to cause no skin irritation or allergic reaction even with prolonged application on human skin, with reasonable expectation of having a patch

comprising adhesive polymer layer comprising hydrocolloid, hyaluronic acid, chondroitin sulfate and saccharose that promotes wound healing and has excellent adhesion and no skin irritation on prolonged use.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis A Ghali
Primary Examiner
Art Unit 1615

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